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PTO/SB/01 (12-97)  
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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney D ck t Number **INTR US-4**

First Named Inventor **Irving K. Arenberg**

**COMPLETE IF KNOWN**

Application Number

/

Filing Date

Group Art Unit

Examiner Name

**As a below named inventor, I hereby declare that:**

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**CONTROLLED RELEASE SYSTEM FOR DELIVERING THERAPEUTIC AGENTS  
INTO THE INNER EAR**

the specification of which

(Title of the Invention)

☒ is attached hereto  
OR

☐ was filed on (MM/DD/YYYY) as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
N/A			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
N/A		

[Page 1 of 2

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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## DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
N/A		

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

☐ Customer Number

OR

☒ Registered practitioner(s) name/registration number listed below

Place Customer Number Bar Code Label here

Name	Registration Number	Name	Registration Number
William P. O'Meara, Esq.	29,962	Bruce E. Dahl, Esq.	33,670
Jay K. Malkin, Esq.	31,393	Michael A. Goodwin, Esq.	32,697
Joseph J. Kelly, Esq.	18,280	Gregory W. Osterloth, Esq.	36,232

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label

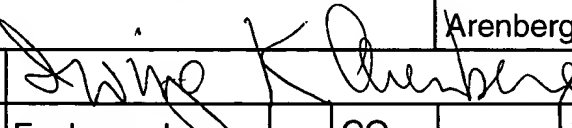
OR ☒ Correspondence address below

Name	Jay K. Malkin				
Address	KLAAS, LAW, O'MEARA AND MALKIN, P.C.				
Address	1999 Broadway, Suite 2225				
City	Denver	State	CO	ZIP	80202
Country	U.S.A.	Telephone	(303) 298-9888	Fax	(303) 297-2266

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))		Family Name or Surname	
Irving K.		Arenberg	
Inventor's Signature			Date
Residence: City		State	Citizenship
Englewood		CO	U.S.A.
Post Office Address			
5860 Goldsmith Place			
Post Office Address			
5860 Goldsmith Place			
City	State	ZIP	Country
Englewood	CO	80111	U.S.A.

☒ Additional inventors are being named on the 1 supplemental Additional-Inventor(s) sheet(s) PTO/SB/02A attached hereto

Please type a plus sign (+) inside this box → +

PTO/SB/02A (3-97)  
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## DECLARATION

**ADDITIONAL INVENTOR(S)**  
**Supplemental Sheet**  
Page 3 of 3

<b>Name of Additional Joint Inventor, if any:</b>				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Michael H.				Arenberg			
Inventor's Signature	<i>Michael H. Arenberg</i>			Date		12/3/98	
Residence: City	Englewood	State	CO	Country	U.S.A.	Citizenship	U.S.A.
Post Office Address	6325 S. Florence Way						
Post Office Address	6325 S. Florence Way						
City	Englewood	State	CO	ZIP	80111	Country	U.S.A.
<b>Name of Additional Joint Inventor, if any:</b>				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Christine				Lemke			
Inventor's Signature	<i>Christine Lemke</i>			Date		12/3/98	
Residence: City	Denver	State	CO	Country	U.S.A.	Citizenship	German
Post Office Address	7565 E. Harvard Avenue, #307						
Post Office Address	7565 E. Harvard Avenue, #307						
City	Denver	State	CO	ZIP	80231	Country	U.S.A.
<b>Name of Additional Joint Inventor, if any:</b>				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
John A.				Berglund			
Inventor's Signature	<i>John A. Berglund</i>			Date		12/3/98	
Residence: City	Lafayette	State	CO	Country	U.S.A.	Citizenship	U.S.A.
Post Office Address	310 1/2 E. Cleveland Street						
Post Office Address	310 1/2 E. Cleveland Street						
City	Lafayette	State	CO	ZIP	80026	Country	U.S.A.

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**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN**

Docket Number (Optional)  
INTR US-4

Applicant, Patentee, or Identifier: Arenberg et al.

Application or Patent No.: Not Yet Accorded

Filed or Issued: Not Yet Accorded

Title: CONTROLLED RELEASE SYSTEM FOR DELIVERING THERAPEUTIC AGENTS INTO THE INNER EAR

I hereby state that I am

- ☐ the owner of the small business concern identified below:  
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN IntraEAR, Inc,

ADDRESS OF SMALL BUSINESS CONCERN 7995 East Prentice Avenue, Suite 110  
Englewood, Colorado 80111-2710

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

- ☒ the specification filed herewith with title as listed above.  
☐ the application identified above.  
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

- Each person, concern, or organization having any rights in the invention is listed below:  
☒ no such person, concern, or organization exists.  
☐ each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Irving K. Arenberg

TITLE OF PERSON IF OTHER THAN OWNER President

ADDRESS OF PERSON SIGNING 5860 Goldsmith Place, Englewood, Colorado 80111-2710

SIGNATURE

DATE

**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

Docket Number (Optional)  
**INTR US-4**

Applicant, Patentee, or Identifier: Arenberg et al.

Application or Patent No.: Not Yet Accorded

Filed or Issued: Not Yet Accorded

Title: CONTROLLED RELEASE SYSTEM FOR DELIVERING THERAPEUTIC AGENTS INTO THE INNER EAR

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- ☒ the specification filed herewith with title as listed above.  
☐ the application identified above.  
☐ the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☐ No such person, concern, or organization exists.  
☒ Each such person, concern, or organization is listed below.

IntraEAR, Inc.  
7995 East Prentice Avenue, Suite 110  
Englewood, Colorado 80111-2710

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

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Irving K. Arenberg  
NAME OF INVENTOR

Irving K. Arenberg  
Signature of inventor

12/3/98  
Date

Michael H. Arenberg  
NAME OF INVENTOR

Michael H. Arenberg  
Signature of inventor

12/3/98  
Date

Christine Lemke  
NAME OF INVENTOR

Christine Lemke  
Signature of inventor

12/3/98  
Date

**STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

Docket Number (Optional)  
**INTR US-4**

Applicant, Patentee, or Identifier: Arenberg et al.

Application or Patent No.: Not Yet Accorded

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- ☒ the specification filed herewith with title as listed above.  
☐ the application identified above.  
☐ the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☐ No such person, concern, or organization exists.  
☒ Each such person, concern, or organization is listed below.  
IntraEAR, Inc.  
7995 East Prentice Avenue, Suite 110  
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**John A. Berglund**

NAME OF INVENTOR

NAME OF INVENTOR

NAME OF INVENTOR

John A. Berglund  
Signature of inventor

Signature of inventor

Signature of inventor

Q.B. 12/3/98  
Date

Date

Date